

unstable in aqueous solution when at 20° C;

wherein said at least one material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said step of forming comprises heating the combined carrier substance and purified biologically active material to a temperature not exceeding 80° C.

18. The process of claim 17 wherein said step of forming comprises maintaining a sub atmospheric pressure on the combined carrier substance and purified biologically active material while heating the combination to at least 30° C and not exceeding 80° C.

19. The process of claim 17 wherein said carrier substance comprises a water soluble or water swellable synthetic polymer.

20. The process of claim 17 wherein said purified biologically active material is not an enzyme.

21. The process of claim 17 wherein said purified biologically active material is not rennin.

22. The process of claim 17 wherein said purified biologically active material comprises a hormone.

23. The process of claim 17 wherein said purified biologically active material comprises immunoglobulin.

24. The process of claim 17 wherein said purified biologically active material comprises a blood clotting factor.

25. The process of claim 17 wherein said purified biologically active material comprises a pharmacologically active protein.

26. A glassy state composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said amorphous carrier substance;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C;

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 2:1 and about 1:1.

27. The composition of claim 26 wherein said composition contains no more than four weight percent water.

28. The composition of claim 26 wherein said ratio is about 2:1.

29. The composition of claim 26 wherein said ratio is about 1:1.

30. The composition of claim 26 wherein said biologically active material is not an enzyme.

31. The composition of claim 26 wherein said biologically active material is not rennin.

32. A method of rendering a material storage stable at 20° C which material is unstable in aqueous solution at room temperature of 20° C, comprising the steps of:

(1) dissolving to form an aqueous solution

(a) said material and

(b) a carrier substance which is water-soluble or water-swella-

ble;
(2) evaporating liquid water from said solution thereby converting said solution into a glassy state composition;

wherein said material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition has the property that it is storage stable and exists in said glassy state when at 20° C; and

wherein a weight ratio of said purified biologically active material to said carrier substance is between about 1:2 and about 1:1.

33. The method of claim 32 wherein said weight ratio is about 1:1.

34. The method of claim 32 wherein said weight ratio is about 1:2.

35. The method of claim 32 wherein said composition contains no more than 4

weight percent water.

36. The method of claim 32 wherein said biologically active material is not an enzyme.

37. The method of claim 32 wherein said biologically active material is not rennin.

38. A method of forming a composition which is storage-stable at 20° C, said composition comprising:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellaable and

(b) at least one material to be stored;

(2) forming said solution containing said carrier substance with said at least one material dissolved therein into a glassy state by evaporation of liquid water to produce said composition;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said composition contains no more than 4 percent by weight of water; and

wherein said composition has the properties that it is storage stable and exists in a glassy state when at 20° C, and

wherein said step of dissolving comprises dissolving in an aqueous solution having a pH of about 7.

B2
Cont.

39. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swella-ble and is in a glassy state;

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition exists in a glassy state at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said purified biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not rennin.

40. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swella-ble;

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not an enzyme.

41. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said composition contains no more than 4 percent by weight of water; and

wherein said biologically active material is not rennin.

42. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides,

enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said biologically active material is not an enzyme; and

wherein said carrier substance does not comprise maltotriose.

43. A composition which is storage-stable at 20° C, comprising:

(1) a carrier substance which is water-soluble or water-swellaable and

(2) at least one material to be stored which is dissolved in said carrier substance;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides,

enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto; and

wherein said biologically active material is not an enzyme and is not freeze stable.

44. A method of forming a composition which is storage-stable at 20° C, comprising the steps of:

(1) dissolving to form an aqueous solution

(a) a carrier substance which is water-soluble or water-swellaable and

(b) at least one material to be stored;

forming said solution into a glassy state composition by evaporating liquid water;

wherein said composition has the property that it exists in a glassy state when at 20° C;

wherein said at least one material comprises a purified biologically active material that is unstable in aqueous solution at 20° C;

wherein said biologically active material is selected from the group consisting of peptides, proteins, nucleosides, nucleotides, dimers or oligomers of nucleosides or nucleotides, enzymes, enzyme cofactors and derivatives of any of the foregoing, said derivatives having one or more additional moieties bound thereto;

wherein said biologically active material is not an enzyme; and

wherein said carrier substance does not comprise maltotriose.

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conclude